Official Title:	ATTENUATE (rAdpad proTecTion drapE iN redUcing rAdiaTion Exposure) Trial
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Version Number	Version Date	Summary of Revisions Made
1.0	3 JAN 2024	Original version

ATTENUATE TRIAL

(rAdpad proTecTion drapE iN redUcing rAdiaTion Exposure)

Principal Investigator:	Giorgio A. Medranda, MD Department of Medicine 259 First Street Mineola, NY 11501 Giorgio.Medranda@nyulangone.org 516 877-2626
NYULMC Study Number:	s23-01408
Study Product:	Protective scatter-radiation absorbing shield, RADPAD protection drape.
Study Product Provider: [If applicable]	NYU Langone Hospital - Long Island
ClinicalTrials.gov Number	Pending.

Initial version: 3 January 2024
Amended:

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations (CFR) on the Protection of Human Subjects (45 CFR Part 46), 21 CFR Parts 50, 56, 312, and 812 as applicable, any other applicable US government research regulations, and institutional research policies and procedures. The International Conference on Harmonisation ("ICH") Guideline for Good Clinical Practice ("GCP") (sometimes referred to as "ICH-GCP" or "E6") will be applied only to the extent that it is compatible with Food and Drug Administration (FDA) and DHHS regulations. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

Table of Contents

Be sure to update the table of contents when you are finished creating your protocol. You can do this in Microsoft Word by going to the References tab and clicking on “Update Table” in the Table of Contents section.

List of Abbreviations

AE	Adverse event/adverse experience
ALARA	As low as reasonably achievable
CCL	Cardiac catheterization laboratory
CFR	Code of federal regulations
CRF	Case report form
CSOC	Clinical study oversight committee
DAP	Dose area product
DCC	Data coordinating center
DHHS	Department of health and human services
DSA	Digital subtraction angiography
DSMB	Data and safety monitoring board
eCRF	Electronic clinical report form
FFR	Federal financial report
FT	Fluoroscopy time
FWA	Federalwide assurance
GCP	Good clinical practice
HIPAA	Health insurance portability and accountability act
ICF	Informed consent form
ICH	International conference on harmonisation
IEC	Independent ethics committee
IRB	Institutional review board
ISM	Independent safety monitor
ITT	Intention to treat
MOP	Manual of procedures
N	Number (typically refers to participants)
NIH	National institutes of health
OE	Operator exposure
OHRP	Office for human research protections
OHSR	Office of Human Subjects Research
PI	Principal investigator
QA	Quality assurance
QC	Quality control
SAE	Serious adverse event/serious adverse experience

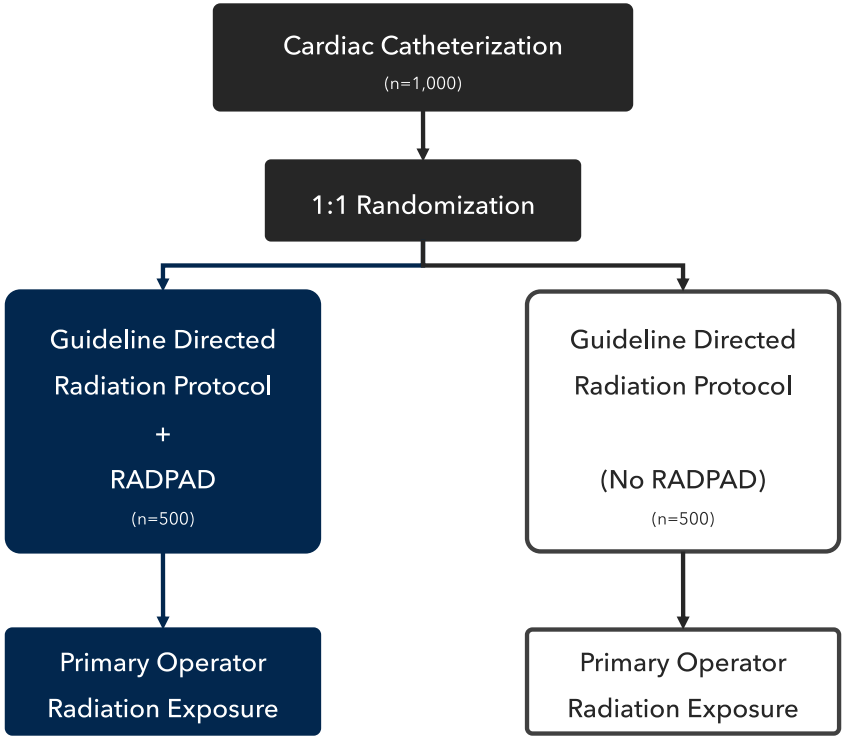
SOP	Standard operating procedure
TD	Total dose
US	United States

Protocol Summary

Title	ATTENUATE (rAdpad proTecTion drapE iN redUcing rAdiaTion Exposure) Trial
Short Title	ATTENUATE Trial
Brief Summary	Despite improvements in radiation safety, interventional cardiologists are increasingly exposed to radiation during cardiac catheterization procedures. The RADPAD protection drape was designed as a protective scatter-radiation absorbing shield with the goal of reducing scatter radiation. It is a sterile, lead free, light weight, and disposable radiation protection shield that is placed directly over the sterile patient drapes. The RADPAD is comprised of antimony and bismuth providing protection during low-energy fluoroscopy and high-energy cine and digital subtraction angiography (DSA) settings. Early and smaller studies have demonstrated a ~20% relative reduction in scatter radiation, with the majority of scatter reduction for the main operator, followed by other personnel and the patient(1-4). The purpose of the ATTENUATE (rAdpad proTecTion drapE iN redUcing rAdiaTion Exposure) Trial is to examine the impact of the RADPAD in a contemporary cardiac catheterization laboratory (CCL), during diagnostic, coronary and structural cardiac catheterization procedures, in a large prospective, randomized controlled trial.
Objectives	Elucidate the degree of reduction in relative exposure to the proximal operator using the RADPAD in a contemporary CCL practice.
Methodology	Prospective, Randomized Controlled Trial
Endpoint	Operator exposure (OE)/dose area product (DAP) (uSv/mGy*cm^2) of the proximal operator between procedures in which guideline directed radiation protocols and the RADPAD was utilized vs. those in which only guideline directed radiation protocols were utilized.
Study Duration	Up to 5 years.
Participant Duration	1 Day.
Duration of IP administration	N/A
Population	Proximal operator of cardiac catheterization procedures and patient cases (patients undergoing the cardiac catheterization procedures)

Study Sites	NYU Langone Hospital - Long Island
Number of participants	Up to 1,000 patient-cases and up to 100 proximal operator-subjects expected to be enrolled across 1 site. The proximal operator cohort is expected to include a few interventional cardiologist attending physicians, interventional cardiology fellows, cardiovascular disease fellows and physician assistants performing multiple cases each, which in total would amount to 1,000 cases performed by 100 proximal operators.
Description of Study Agent/Procedure	The RADPAD protection drape was designed as a protective scatter-radiation absorbing shield with the goal of reducing scatter radiation. It is a sterile, lead free, light weight, and disposable radiation protection shield that is placed directly over the sterile patient drapes. The RADPAD is comprised of antimony and bismuth providing protection during low-energy fluoroscopy and high-energy cine and DSA settings.
Reference Therapy	N/A
Key Procedures	Cardiac catheterization radiation data acquisition.
Statistical Analysis	The study will be analyzed using comparative statistics.

Schematic of Study Design



1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

As the field of interventional cardiology continues to expand, highlighted by the meteoric rise of transcatheter structural interventions, ionizing radiation exposure and its associated risk is expected to increase. Ultimately, the goal must be to acquire the clinical information necessary while keeping radiation doses as low as reasonably achievable (ALARA). As a result, there is renewed interest in establishing a culture of radiation safety in many CCLs across the country(5).

Developing evidence-based strategies aimed at lowering radiation exposure to patients, CCL staff, and physicians, fueled by advances in the field of radiation safety, is of paramount importance to promote longevity and accomplish this endeavor. Among these measures are several which have been proven and implemented as standard of care(6-16). Novel adjunct techniques and equipment continue to emerge and have garnered attention over the last decade such as the RADPAD.

2.2 Name and Description of the Investigational Device

The RADPAD protection drape was designed as a protective scatter-radiation absorbing shield with the goal of reducing scatter radiation. It is a sterile, lead free, light weight, and disposable radiation protection shield that is placed directly over the sterile patient drapes. The RADPAD is comprised of antimony and bismuth providing protection during low-energy fluoroscopy and high-energy cine and DSA settings. Early and smaller

studies of the RADPAD have demonstrated a ~20% relative reduction in scatter radiation, with the majority of scatter reduction for the main operator, followed by other personnel and the patient(1-4). The RADPAD is FDA-approved and is used in accordance with its indications.

2.3 Rationale

The RADPAD protection drape was designed as a protective scatter-radiation absorbing shield with the goal of reducing scatter radiation. It is a sterile, lead free, light weight, and disposable radiation protection shield that is placed directly over the sterile patient drapes. The RADPAD is comprised of antimony and bismuth providing protection during low-energy fluoroscopy and high-energy cine and DSA settings. Early and smaller studies have demonstrated a ~20% relative reduction in scatter radiation, with the majority of scatter reduction for the main operator, followed by other personnel and the patient(1-4). Universal adoption and uptake of the RADPAD in radiation safety guidelines and protocols has not occurred. Furthermore, the impact of the RADPAD protection drape in a contemporary CCL remains unclear. Thus, the purpose of the ATTENUATE Trial is to examine the impact of the RADPAD in a contemporary CCL, during diagnostic, coronary and structural cardiac catheterization cases, in a large prospective, randomized controlled trial.

2.4 Potential Risks & Benefits

2.4.1 Known Potential Risks

This study involves no more than minimal risk to the proximal operator subjects and patient-cases of the procedure. All proximal operators of each cardiac catheterization procedure enrolled (subjects), will practice radiation safety according to the standard of care utilizing guideline directed radiation protocols as dictated by the local Department of Medical Physics/Radiation Safety regardless of the arm in which they are randomized to. There are no known risks related to the use of the RADPAD. The risk of not using the RADPAD is no different than standard of care.

The patients undergoing the cardiac catheterization procedure by the proximal operators (subjects) will do so with no alterations in the quality or method of care delivered to them.

2.4.2 Known Potential Benefits

While there are no anticipated direct benefits to individual subjects, the potential benefits of the proposed study and aggregation of data far outweigh the potential for any breaches in confidentiality as discussed above. In addition, investigators are not proposing to perform any additional procedures or adjustments to procedures that would not be allowable under other circumstances.

We believe that this study will contribute to the knowledge of radiation safety in this contemporary era of interventional cardiology. The results of this study may be useful to regulatory agencies like the FDA, investigators, the device industry, physicians and CCL staff, and may help guide future clinical guidelines for radiations safety in the CCL.

3 Objectives and Purpose

3.1 Primary Objective

Elucidate the degree of reduction in relative exposure to the proximal operator using the RADPAD in a contemporary CCL practice.

4 Study Design and Endpoints

4.1 Description of Study Design

This is a prospective, randomized controlled trial that will enroll proximal operators performing cardiac catheterization procedures and randomize them prior to the procedure using computer-based simple randomization to use of the standard guideline directed radiation protocols with RADPAD vs. standard guideline directed radiation protocols alone.

4.2 Study Endpoints

4.2.1 Primary Study Endpoints

The primary study endpoint is OE/DAP (uSv/mGy*cm2) of the proximal operator between procedures in which guideline directed radiation protocols and the RADPAD was utilized vs. those in which only guideline directed radiation protocols were utilized. This endpoint measures the operator's radiation exposure while accounting for the amount of radiation used during any given cardiac catheterization procedure, which is known to vary depending on the duration of the case and the patient characteristics. This is the most common primary endpoint utilized in similar smaller and older studies.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria (Employees)

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

a) Proximal operator of a cardiac catheterization procedure as defined by the individual performing the procedure closest to the source of radiation. This may be either physician assistants of the CCL, fellows of cardiovascular disease, interventional cardiology fellows or attending interventional cardiologists at NYU Langone Hospital - Long Island.

b) Age ≥18 years

c) Willing and able to consent.

5.2 Exclusion Criteria (Employees)

An individual who meets any of the following criteria will be excluded from participation in this study:

a) Anyone unable or unwilling to give informed consent.

b) Anyone pregnant or breastfeeding.

c) A proximal operator performing a cardiac catheterization procedure where there are not located on the right-side of the patient and/or behind the radiation shield.

d) Any proximal operator who wishes to use the RADPAD regardless of being in the study/is unwilling to be randomized

Inclusion Criteria: Patient Cases
In order for a case to be eligible to be included in this study, it must meet all of the following criteria:

a) Cardiac catheterization procedure at NYU Langone Hospital – Long Island.

b) Age ≥18 years of the patient undergoing cardiac catheterization.

Exclusion Criteria: Patient Cases
There are no specific exclusion criteria that pertain exclusively to the cardiac catheterization procedure.

5.3 Vulnerable Subjects

This study examines radiation exposure to employees (proximal operators) during cardiac catheterization procedures thus it is scientifically necessary to enroll employees to conduct this study. Radiation is already routinely measured for all who work in the CCL by the Department of Medical Physics/Radiation Safety and utilization of the RADPAD protection drape contributes an insignificant amount of time (seconds) to the preparation of a cardiac catheterization procedure. The proximal operator-Participants' decision to participate or to withdraw from the study will not impact their employment, salary, and/or performance evaluation as no one in a supervisory role is recruiting for this study. Proximal operators who wish to use the RADPAD regardless of participation in the study will be informed that they may choose not to be in the study and elect to use the RADPAD per their preference.

5.4 Strategies for Recruitment and Retention

Recruitment will occur in person by the PI and will be without coercion with verbal consent and a waiver of documentation of consent which includes the key information document and biomedical consent form. Recruitment will begin in January of 2024 upon IRB approval. Recruitment will begin in aggregate based on the various personnel who may be involved in the relevant procedures. The PI will schedule brief educational

sessions to describe the study. Subjects will be reminded that they can withdraw at anytime by contacting PI. Subjects who give verbal consent will participate in the study. This will give the personnel sufficient time to understand the study and consent prior to cardiac catheterization procedures as to not delay patient care.

Since the only patient level data obtained will be de-identified data points with no need to record PHI in the record, patient-subjects will not be approached for recruitment, rather they will be enrolled using a waiver consent and authorization.

The PI is the only person involved in recruitment and informed consent process for the proximal operator subjects. The PI does not have any supervisory role over the relevant personnel who may be eligible to participate in the study as proximal operators.

5.5 Duration of Study Participation

Subjects enrolled will participate in this study for the duration of the cardiac catheterization procedure (less than one day).

5.6 Total Number of Participants and Sites

The study will seek to include up to 1,000 cardiac catheterization procedures (cases) being performed by up to 100 proximal operators with an expected duration of the study of up to 5 years.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.7.2 Handling of Participant Withdrawals or Termination

There is no scheduled follow-up in this study as there are no adverse events are expected from this study (as it is minimal risk). The biggest risk that could occur is a breach of confidentiality. Once a participant withdraws their data will be deleted and excluded from this study.

5.8 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to investigator and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the sponsor, IRB and/or FDA.

6 Study Device and/or Procedural Intervention

6.1 Study Device and Control Description

The RADPAD protection drape was designed as a protective scatter-radiation absorbing shield with the goal of reducing scatter radiation. It is a sterile, lead free, light weight, and disposable radiation protection shield that is placed directly over the sterile patient drapes. The RADPAD is comprised of antimony and bismuth providing protection during low-energy fluoroscopy and high-energy cine and DSA settings. This study will enroll proximal operators performing cardiac catheterization procedures and randomize them prior to the procedure using computer-based simple randomization to use of the standard guideline directed radiation protocols with RADPAD vs. standard guideline directed radiation protocols alone.

6.1.1 Acquisition

The RADPAD is routinely stocked and available to all interventional cardiologists for use in all CCLs at NYU Langone Hospital – Long Island.

6.1.2 Device Specific Considerations

There are several models of RADPAD that are FDA-approved and used throughout CCLs in the country. This study will utilize the RADPAD® ORANGE Peripheral Shield (11”x 34”) as this is among the most used in other CCLs and the model currently approved and used in procedures at NYU Langone Hospital and NYU Langone Hospital – Brooklyn. Examining the utility of other specific models in addition to this one would not be expected to offer any additional meaningful insight to the study question.

7 Study Procedures and Schedule

7.1 Study Procedures/Evaluations

7.1.1 Study Specific Procedures

- For those randomized to the RADPAD arm, a single RADPAD® ORANGE Peripheral Shield will be placed on the patient's drape in a sterile fashion according to the manufacturer's instructions for use prior to commencement of the procedure.
- All employee participants will wear a radiation detection device at the level of the left side of the chest facing the radiation source over any the protective apron worn by the participant, provided by the Department of Medical Physics/Radiation Safety.
- Medical history of the patients undergoing cardiac catheterization will be collected on the day of procedure using the medical record without collection of patient-specific identifiers. This information is important to collect to allow interventional cardiologists outside of our institution to understand our patient population as certain co-morbidities affect the amount of radiation operators are exposed to.
- Radiation data and date/type of each cardiac catheterization procedure each participant performs will be collected on the day of procedure using the medical record without collection of participant-specific identifiers.

7.1.2 Standard of Care Study Procedures

Each cardiac catheterization procedure utilizes the standard guideline directed radiation protocol to minimize the risk of ionizing radiation to all CCL staff as defined by the Department of Medical Physics/Radiation Safety. This includes, but is not limited to use of the following equipment:

- Shielded skirt beneath the procedure table
- Mobile hanging or grounded radiation shields
- Personal protective equipment such as thyroid collars, and aprons (standard or suspended)

7.2 Study Schedule

The only evaluation in this study will be performed on the day of the cardiac catheterization procedure.

7.2.1 Screening

Screening will occur prior to each cardiac catheterization procedure as described above.

8 Assessment of Safety

No adverse events are expected from this study, as it is minimal risk, the biggest risk that could occur is a breach of confidentiality. If breach of confidentiality occurs, the IRB will be notified immediately.

8.1 Safety Oversight

The Principal Investigator will be responsible to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Adverse events will be reviewed on the quarterly basis. There are no stopping rules. An annual report will be submitted to the IRB with the continuing review submission.

9 Clinical Monitoring

Clinical site monitoring will be conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

- Monitoring for this study will be performed on-site quarterly by the Principal Investigator with 100% data verification.

10 Statistical Considerations

10.1 Statistical and Analytical Plans (SAP)

The study will be analyzed using comparative statistics without use of a formal SAP.

10.2 Statistical Hypotheses

The objective of the statistical analysis of the data generated is to assess the degree of radiation exposure reduction with use of the RADPAD during cardiac catheterization procedures.

10.3 Analysis Datasets

Two cohorts will be analyzed based on simple randomization using an Intention-to-Treat (ITT) analysis dataset.

10.4 Description of Statistical Methods

10.4.1 General Approach

The study will present categorical and continuous data as percentages and means (with standard deviations), respectively. Inferential tests will be considered significant if the p-value is <0.05.

10.4.2 Analysis of the Primary Efficacy Endpoint(s)

The primary study endpoint is OE/DAP (uSv/mGy*cm2) of the proximal operator between procedures in which guideline directed radiation protocols and the RADPAD was utilized vs. those in which only guideline directed radiation protocols were utilized. This endpoint measures the operator's radiation exposure while accounting for the amount of radiation used during any given cardiac catheterization procedure, which is known to vary depending on the duration of the case and the patient characteristics. This is the most common primary endpoint utilized in similar smaller and older studies. This is a continuous variable which will be analyzed statistically using the student's t-test.

10.5 Sample Size

The study expects to enroll up to 100 proximal operators (up to 100 proximal operators performing up to 1,000 cardiac catheterization procedures on up to 1,000 patients). This number of operators are expected to perform that number of cardiac catheterization procedures to meet the study's objectives. Sample size in this study is not driven by statistical requirements.

10.6 Measures to Minimize Bias

10.6.1 Enrollment/Randomization/Masking Procedures

This study will utilize computer-based simple randomization to RADPAD or no RADPAD without use of a sham product or blinding as all cardiac catheterization procedures are expected to produce variable amounts of radiation and the primary outcome adjusts the proximal OE for this variation. Thus, both sham products and blinding is considered unnecessary.

11 Source Documents and Access to Source Data/Documents

Electronic case report forms (eCRF) will be completed for each study subject. It is the Principal Investigator's responsibility to ensure the accuracy, completeness, and timeliness of the data reported in the subject's eCRF. The Principal Investigator will complete the eCRF forms as soon as possible after information is collected. Source documents for the study include the eCRF and patient medical records.

12 Quality Assurance and Quality Control

Quality control procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated for clarification/resolution. Additionally, quality control of the radiation detection device is performed regularly at intervals determined by the Department of Medical Physics/Radiation Safety.

13 Ethics/Protection of Human Subjects

13.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

13.3 Informed Consent Process

13.3.1 Consent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study device, study procedures, and risks are given to the participant however written documentation of informed consent will not be required prior to enrolling. The following consent materials are submitted with this protocol

- Key Information Form
- Biomedical Consent Form

13.3.2 Consent Procedures and Documentation

Recruitment and informed consent will occur in person by the PI and will be without coercion with verbal consent and a waiver of documentation of consent which includes the key information document and biomedical consent form script. The PI does not have a supervisory role over any of the potentially eligible employee subjects (proximal operators). Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the consent form and ask questions prior to consenting. The participants should have the opportunity to discuss the study with or think about it prior to agreeing to participate. The participants may withdraw consent at any time throughout the course of the trial. A copy of the key info sheet and consent script will be given to the participants for their records. The principal investigator will keep documentation of all consent processes in the study's regulatory binder. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

Recruitment will begin in January of 2024 upon IRB approval. Recruitment will begin in aggregate based on the various personnel who may be involved in the relevant procedures. The PI will schedule brief educational sessions to describe the study. Subjects will be reminded that they can withdraw at anytime by contacting PI. Subjects who give verbal consent will participate in the study. This will give the personnel sufficient time to understand the study and consent prior to cardiac catheterization procedures as to not delay patient care.

Since the only patient level data obtained will be de-identified data points with no need to record PHI in the record, subjects will not be approached for recruitment, rather they will be enrolled using a waiver consent and authorization.

Waiver of documentation of consent (employee subjects):

The only record linking a subject to the study is the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Additionally, the study presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (RADPAD is utilized outside of this study at each operators discretion and is FDA-approved).

Waiver of Consent and Health Insurance Portability and Accountability Act (HIPAA) (patient subjects):

With regards to the waiver of consent, for the patient data collected, this involved no more than minimal risk to the patients. The research could not be practically carried out for 1,000 patients without the requested waiver. This waiver does not adversely affect the rights and welfare of the patients undergoing cardiac catheterization procedures. With regards to the waiver of authorization, there will be no collection of protected health information of the patients undergoing cardiac catheterization procedures.

13.4 Participant and Data Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover research and clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB or pharmaceutical company supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant’s contact information will be securely stored at the site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be stored at NYU Langone Hospital- Long Island. This will not include the participant’s contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by NYU

Langone Hospital -Long Island research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NYU Langone Hospital – Long Island.

13.5 Secondary Future Use of Stored Data

Future use of data will not occur outside the scope of this study and its estimated duration.

14 Data Handling and Record Keeping

The following subsections should include a description of the data handling and record keeping for the conduct of the trial.

14.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into REDCap. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

14.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close-out, 5 years after final reporting/publication, or 2 years after the last approval of a marketing application is approved for the device for the indication for which it is being investigated or 2 years after the investigation is discontinued and FDA is notified if no application is to be filed or if the application has not been approved for such indication. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site PI/study staff to use continuous vigilance to identify and report deviations in accordance with NYULH HRP Policies and Procedures.

All protocol deviations must be addressed in study source documents.

Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

14.4 Publication and Data Sharing Policy

It is anticipated that the results of this study will be presented at scientific meetings and/or published in a peer reviewed scientific or medical journals.

15 Study Finances

15.1 Funding Source

There are no funding sources for this study.

15.2 Costs to the Participant

There is no cost to participate in this study.

15.3 Participant Reimbursements or Payments

There are no participant reimbursements or payments.

16 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Management Unit (CIMU) with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULH investigators will follow the applicable conflict of interest policies.

17 References

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18 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

- Verbal Consent Script
- Key Information Form
- Application for Waiver of Authorization and Consent: Patient Subjects
- Application for Waiver of Documentation of Consent: Employee Subjects